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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,896	09/16/2003	Christoph Reinhard	59516-57 / PP-01524.103	4159

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,896	REINHARD, CHRISTOPH	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group IV, claim 16, in the reply filed on 10/28/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Claim 16 is under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim is directed toward a method of using SEQ ID NOs: 1, 3, 5, or 7 for diagnosing or prognosing any and all types of neoplasia. Applicants disclose the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5, and SEQ ID NO: 7 and the deduced amino acid sequences of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8. Applicants disclose that based on homology searches that the protein comprising SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8 has cyclin-dependent kinase activity which is termed hPNQALRE. Assignment of kinase activity to the protein is a generic asserted utility, where kinases are known in the art to have diverse biological functions and substrate specificities.

The specification does not specifically disclose the specific function of the protein or its relationship to any disease. The specification does not specifically disclose homology alignments to known cyclin-dependent kinases. The specification generally states on page 4, line 20 through page 5, line 8 that two regulatory amino acid residues at the N-terminus of the protein which are found in cdk2 are replaced by alanine and histidine at position 14 and position 15 and that the cyclin binding domain is replaced by PNQALRE (SEQ ID NO: 5).

The state of the state of the art in protein function prediction from protein amino acid sequence and structure is reviewed by Whisstock et al. (Q Rev Biophys. 2003 Aug;36(3):307-40).

Whisstock et al. teach (1) protein function prediction is a difficult problem since homologous proteins often have different and multiple functions; (2) methods for inferring function based on similarity in sequence and/or structure between an unknown protein and one or more well-understood proteins is tenuous and only provide guesses at function; (3) protein function predictions suggest function but do not determine function; (4) the most useful effect of protein function prediction is to guide laboratory experimentation to confirm, refute, or correct the prediction; and (5) protein function prediction from protein sequence and structure is useful but is not a substitute for laboratory experimentation (see entire publication, especially pp. 321-335).

A "specific utility" is specific to the subject matter claimed which contrasts with a general utility that would be applicable to the broad class of the invention. "Substantial utility" is one that provides a specific benefit in currently available form at the time of filing of the invention. Utilities that require or constitute carrying out further research to identify and/or reasonably confirm a specific use are not substantial and do not provide a specific benefit. Since kinases are known in the art to have diverse biological functions and substrate specificities, it appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function, substrate specificity, and possible diseases associated with the protein. Thus, the claimed invention for using the recited polynucleotide of SEQ ID NOs: 1, 3, 5, and 7 has no specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 16 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claim is directed toward a method of using SEQ ID NOs: 1, 3, 5, or 7 for diagnosing or prognosing any and all types of neoplasia, where such types of neoplasia include melanomas, squamous cell carcinomas, and breast tumors. However, the specification does not provide

guidance, prediction, and working examples showing that the recited polynucleotides can be used in diagnosing or prognosing any and all types of neoplasia.

While the specification states in Example 1 that hPNQALRE mRNA were expressed in higher levels in cancer cell lines K565, A549, G361, and SW480, the specification does not describe a correlation between increased expression of hPNQALRE mRNA with identification to any and all types of neoplasia. The specification does not describe any correlation between increased expression of hPNQALRE mRNA and prediction about the prospects of recovery in patients having any neoplasia including breast cancer.

Molina et al. (Tumour Biol. 2005 Oct 25;26(6):281-293) teach that to date the only known tumor markers used in the diagnosis and prognosis of breast cancer are MUC-1 mucin glycoproteins, estrogen receptor, progesterone receptor, and HER-2. However, the diagnostic and predictive impact of increased expression of hPNQALRE mRNA and breast cancer or any other neoplasia has not been established by the specification. Thus, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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